REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks.

I. CLAIM STATUS

Claims 39-40, 42, 48, and 50 were pending in this application when last examined.

Claims 1-38, 41, 43-47, and 49 stood cancelled without prejudice or disclaimer thereto.

Claims 39-40, 42, 48, and 50 were examined on the merits and stand rejected.

II. REJECTION UNDER 35 USC 103(a)

Beginning on page 2 of the Office Action, claims 39-40, 42, 48, and 50 are rejected under 35 USC 103(a) as anticipated by Kato et al. (US 2004/0022938; US 10/398,222).

Applicants respectfully traverse this rejection as applied to the claims.

The technical feature of current claim 39, is

"dispersing or dissolving one or more substance(s) selected from plasmids and siRNA and an anionic polymer in a liquid with lead particles, wherein the lead particles comprise a lipid assembly, liposome, an emulsion particle or a polymeric micelle,".

The Examiner notes "Although Kato et al. does not expressly describe a complex of plasmid or siRNA, liposome and anionic polymer, Kato et al. discloses a method for coating fine particles with lipid membrane, wherein the fine particles comprise a complex of a drug, liposome containing phospholipid and a dextran sulfate sodium salt.... Therefore, the selection of plasmid or siRNA as the nucleic acid in the complexes of claimed invention is simply a matter of design."

Kato et al. teaches that a nucleic acid is one of the drug, the drug including substances having a pharmacological activity such as a protein including enzyme, a peptide, a nucleic acid including gene, a low-molecular compound, a saccharide and a polymer compound. Kato et al. expressly describes only cases of G-CSF (protein) as the complex of a drug, liposome containing phospholipid and a dextran sulfate sodium salt.

Kato et al. does not expressly describe not only a complex of plasmid or siRNA, liposome and anionic polymer, but also a complex of nucleic acid, liposome and anionic polymer. Therefore, the combination of nucleic acid, liposome and anionic polymer in the

claimed invention are different from the teachings of Kato et al. and, the selection of plasmid or siRNA is over a design choice.

Further, the Examiner notes "In regards to the increase in efficiency observed due to the presence of anionic polymer in Examples 15-17 of the specification as filed, Applicants have not provide any evidence that this observation is unexpected in light of the teachings of Kato et al."

However, Kato et al. expressly discloses only the combination a nucleic acid with liposome without a dextran sulfate sodium salt. And, Kato et al. expressly describes only cases of fluorescein isothiocyanate-bound phosphorothioated oligonucleotide (F-PS) as the complex of a nucleic acid with liposome.

Kato et al. discloses that all of Example 7-18 are favorable for producing coated complex particles which comprise a nucleic acid with liposome without a dextran sulfate sodium salt. Kato et al. does not teach any problem.

However, in the case of a complex of plasmid or siRNA with liposome, this technique leaves room for improvement.

Examples 13 and 14 in the specification of the application disclose the producing method of coated complex particles which comprise plasmids with liposome without anionic polymer.

Examples 15-19 and 24-27 in the specification of the application disclose that the method of claimed invention is favorable for producing coated complex particles which comprise plasmids and siRNA.

And, as for the preparations containing a dextran sulfate sodium salt (which is an anionic polymer) obtained in Examples 15 to 17, the recovery rates of EPC are roughly not lower than about 50%, which are high, and coating of the complex particles with the coating lipid are efficient, therefore they are preferred to the preparation of Example 13 (without anionic polymer).

[0128] [Table 4]

	Recovery rate (%)	
	Plasmid	EPC
Example 13 (without anionic polymer)	72.9	38.4
Example 15	74.7	68.4
Example 16	98.3	66.8
Example 17	64.5	47.1

In Example 14, the average particles diameter was 320 nm, it is considered that aggregation of complex particles during the production process of the coated complex particles happened in some degree.

[0124] [Table 3]

	Average particles diameter (nm)
Example 13 (without anionic polymer)	96
Example 14 (without anionic polymer)	320
Example 15	117
Example 16	122
Example 17	102
Example 18	97

Accordingly, Applicants believe the invention's observation is unexpected in light of the teachings of Kato et al.

For the above reasons, Applicants respectfully submit that one skilled in the pertinent art would find no reason in the teachings of the cited reference to modify its teachings in order to arrive at the claimed invention, nor would he have any reasonable expectation of success in doing so.

Applicants respectfully submit that the rejection is untenable as applied to the claims and should be withdrawn.

CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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